IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Kagan et al.	) Group Art Unit 3767
Appl. No.	:	10/698,148	)
Filed	:	October 31, 2003	)
For	:	APPARATUS AND METHODS FOR TREATMENT OF MORBID OBESITY	)
Examiner	:	Phillip Gray	

DECLARATION OF CHRISTOPHER THOMPSON UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Dear Sir or Madam:

I, Christopher Thompson, M.D., M.Sc., do declare the following:

1. I am an Assistant Professor in Medicine at Harvard Medical School and the Director of Developmental and Bariatric Endoscopy at Brigham and Women's Hospital in Boston. I received my medical degree and Masters in Health Evaluation Science from the Pennsylvania State University College of Medicine and began my residency and fellowship training at the Penn State University Hospitals in 1996. I then completed a combined Advanced Endoscopy fellowship at Massachusetts General Hospital and Brigham and Women's Hospital. I am also on staff at the Dana Farber Cancer Institute and Children's Hospital Boston, and am the co-director of the Department of Defense funded CIMIT Working Group on Endoscopic Surgery. My mailing address is 75 Francis Street, Boston, MA 02115.

2. I am an active clinician who also has significant research experience in the field of

advanced endoscopy as it applies to bariatric endoscopy, post surgical complications, reflux, and pancreatic disease. I have also established an active animal lab geared toward device development and industry partnering directed to Natural Orifice Transluminal Endoscopic Surgery (NOTES) and the development of endoluminal devices. I am a medical consultant for ValenTx, Inc., the assignee of the present application.

3. I am very familiar with the claimed invention of the above-identified patent application. I understand that in the Office Action mailed July 21, 2008 the Examiner made rejections relying on Bessler (U.S. Patent Pub. No. 2004/0039452 A1), Gannoe (U.S. Patent Pub. No. 2004/0082963), and/or Taylor (U.S. Pat. No. 6,254,262). I have reviewed those references and the Office Action in preparing this Declaration.

4. Bessler teaches a nonpuncturing attachment system, in the form of a self expandable or balloon expandable stent.

5. Gannoe teaches a mucosal to mucosal puncture of a plication, to reduce the diameter of the opening at the base of the esophagus and permit serosa to serosa bonding for long-lasting attachment.

6. Taylor teaches an anti-reflux prosthesis 11 with a tissue anchor array 19 comprised of barbed spikes 25 for piercing and engaging the lumen wall of the esophagus. I would expect barbed spikes 25 as illustrated (e.g., Figs. 6A-6E) and described in Taylor to have the same configuration when passing through the luminal wall compared with after passing through the luminal wall.

7. I see no reason to, and would not consider combining the Bessler and Taylor references to come up with the claimed invention. All disclosed embodiments in Bessler involve an expandable stent that does not penetrate any tissue walls in order to meet its objective of securing the ends of the device within the esophagus. As such, I believe Bessler tends to teach way from the use of a penetrating tissue attachment. Thus, the use of barbed spikes as disclosed in Taylor to secure Bessler's device would be contrary to Bessler's intent of providing a non-penetrating, less traumatic device for gastric bypass.

8. I also see no reason to, and would also not consider combining the Gannoe and Taylor references to come up with the claimed invention. As discussed above, Gannoe's primary

objective is to create a serosa-to-serosa bond via a plication for permanent healing. Eliminating the plication to attach a device through a non-plicated wall as disclosed in Taylor would defeat Gannoe's stated purpose of creating the serosa-to-serosa bond for long-term healing.

9. Furthermore, to my knowledge, prior to the claimed invention, all methods of attaching a device to an attachment site near or at the gastroesophageal junction, with the exception perhaps of esophageal stents in certain cancer patients, have generally resulted in failure. These methods have experienced a myriad of problems such as, for example anchor migration, wall erosion or rupture resulting in undesired device placement or explantation. I would be concerned that attempts to modify such methods and devices in order to remedy these problems would make the devices difficult or dangerous to remove. The stomach's response to the presence of implants is highly unpredictable, and I was thus in fact extremely surprised that the methods claimed, namely attaching the proximal end of a gastrointestinal sleeve transmurally using one or more tissue anchors to a serosal surface at an attachment site near the gastrointestinal junction have been very effective in safely, stably and securely attaching a device to an attachment site near the gastroesophageal junction, as evidenced by both animal trials as well as in human trials (unpublished) performed thus far. I have personally observed multiple procedures conducted by ValenTx and reviewed interval postoperative follow-up results. I would not have predicted the success of the claimed methods and devices from any of the teachings of Bessler, Taylor, or Gannoe raised by the Examiner as a basis for rejection.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Dated: 11-20-08 By: _____
Christopher Thompson, M.D.

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